DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS
Our Reference: 2937270

July 1, 2002

Hee Gon Kim, Vice President
Hanmi, Inc.
3345 E. Slausen Avenue
Vernon, California 90058

WARNING LETTER

Dear Mr. Kim:

On January 11, 16, and 17, 2002, the U.S. Food and Drug Administration (FDA) conducted an inspection of your facility located at 2992 Alvarado Street, #M, San Leandro, California. The inspection was conducted to determine your firm's compliance with FDA's seafood processing regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). A copy of the regulations is enclosed for your ready reference.

We found that you have serious deviations from the regulations cited above. These deviations cause your frozen mackerel and dried squid to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) in that the fish have been prepared, packed, and held under insanitary conditions, whereby they may have been rendered injurious to health.

The observations of concern to us are as follows:

1. You must have product specifications that are designed to ensure that the fish and fishery products you import are not adulterated under section 402 of the Act because they may be injurious to health or because they may have been processed under insanitary conditions, to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have product specifications for frozen mackerel and dried squid products imported from [redacted]

2. You must implement an affirmative step, which ensures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulations, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for frozen mackerel manufactured by [redacted]

[redacted] in [redacted] (Invoice Date: DEC. 18, 2001) or for dried squid manufactured by [redacted] in [redacted] (Invoice Date: FEB. 13, 2001).

With respect to the mackerel you import, your firm has failed to adequately implement the affirmative step you have identified in your verification procedures of maintaining a HACCP plan and a current Letter of Guarantee.

With response to the dried squid you import, you have failed to identify and implement any affirmative step.

At the conclusion of the inspection, the deviations were listed on Form FDA 483 (Inspectional Observations) and discussed with Mr. TaeWon Chong, Branch Manager. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. You are responsible for ensuring that your facility operates in compliance with the Act and the seafood HACCP regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA may detain your imported seafood products without examination.

More than three months have elapsed since FDA inspection. Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct these violations. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your reply relating to these concerns should be directed to the U.S. Food and Drug Administration, Attention: Ms. Harumi Kishida, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070.

If you have questions regarding the implementation of the HACCP regulations, you may contact FDA Investigator, Janice Wai, at (510) 337-6815 for answers and/or direction towards guidance and sources of training in achieving compliance.

Sincerely,

Dennis K. Linsley
District Director
San Francisco District